# IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS AMARILLO DIVISION

FREEDOM COALITION OF DOCTORS FOR CHOICE,

Plaintiff,

v. 2:23-CV-102-Z

CENTERS FOR DISEASE CONTROL AND PREVENTION, et. al.,

Defendants.

#### MEMORANDUM ORDER AND OPINION

Before the Court is Plaintiff's Motion for Summary Judgment (ECF No. 8) ("Motion") and Defendants' Cross Motion for Summary Judgment (ECF No. 27) ("Cross Motion"). For the following reasons, the Motion is **GRANTED** and the Cross Motion is **DENIED**.

#### Introduction

In response to the COVID-19 pandemic, the United States government spearheaded one of the greatest medical endeavors in history. Within months, Congress allocated billions of dollars to fund, develop, manufacture, and distribute hundreds of millions of doses of COVID-19 vaccines. When the first vaccines became available in December of 2020, Defendants launched a massive safety monitoring program called "V-safe." Because of the rapid and extensive rollout of the vaccine, Defendants used V-safe to quickly collect critical health data for symptoms, adverse events, hospitalization or treatment, and safety issues directly from those who received the vaccines. V-safe collected two types of data from millions of Americans: (1) check-the-box options and (2) free-text responses. Plaintiff seeks production of approximately 7.8 million free-text responses pursuant to the Freedom of Information Act ("FOIA").

#### BACKGROUND

#### A. COVID-19 Vaccines and Associated Policies

As COVID-19 spread, the federal government collaborated and cooperated with foreign governments and non-governmental humanitarian organizations, <sup>1</sup> private companies, <sup>2</sup> and the media <sup>3</sup> to enable and incentivize widespread vaccination. Operation Warp Speed, the effort to fast-track COVID-19 vaccines to the American people, removed many of the regulatory and market hurdles for manufacturers while also authorizing vaccines for emergency use. <sup>4</sup> Pursuant to Emergency Use Authorization, the FDA exercised the authority to permit use of unapproved medical products or unapproved uses of otherwise approved products to diagnose, treat, or prevent COVID-19. <sup>5</sup> Beginning in 2020, former Secretary of the U.S. Department of Health and Human Services, Alex Azar II, issued a series of PREP Act Declarations covering COVID-19 tests, drugs, and vaccines. <sup>6</sup> Ultimately, the Declarations provided liability immunity and protections for

<sup>&</sup>lt;sup>1</sup> U.S. Agency for International Development, *Executive Summary: Global Vax: Accelerating COVID-19 Vaccination Efforts Around the World*, Global Vax Initiative for Global COVID-19 Vaccine Access (Sept. 14, 2023) (explaining the \$2 billion global vaccination campaign).

<sup>&</sup>lt;sup>2</sup> For instance, HHS partnered directly with Johnson & Johnson to pump over \$1 billion into the rapid development of the Janssen COVID-19 vaccination. Jon Cohen, *The \$1 billion bet: Pharma giant and U.S. government team up in all-out coronavirus vaccine push*, American Association for the Advancement of Science, available at https://www.science.org/content/article/1-billion-bet-pharma-giant-and-us-government-team-all-out-coronavirus-vaccine-push (Mar. 31, 2020).

<sup>&</sup>lt;sup>3</sup> See, e.g., Missouri v. Biden, 83 F.4th 350, 364 (5th Cir. 2023) (explaining social media censorship in response to White House "pressure," how "platforms continued to amplify or assist . . . a vaccine 'booster' campaign," and how "CDC officials authoritatively told the platforms what was (and was not) misinformation").

<sup>&</sup>lt;sup>4</sup> U.S. Government Accountability Office, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, GAO-21-319 (Feb. 11, 2021).

<sup>&</sup>lt;sup>5</sup> U.S. Food and Drug Administration, *Emergency Use Authorization for Vaccines Explained*, available at https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.

<sup>&</sup>lt;sup>6</sup>See Eleventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 88 Fed. Reg. 30769 (May 12, 2023) (including the most recent update to the COVID PREP Act Declarations and providing a summary of the prior ten Declarations).

manufacturers, distributors, states, localities, healthcare professions, and other qualified persons involved in COVID-19 campaigns.<sup>7</sup>

To say the government promoted vaccination — directly through mandates or indirectly through policies, privileges, and messaging campaigns — would be an understatement. Many Americans' employability was conditioned upon vaccination by various rules, regulations, and policies. For instance, the Biden Administration issued Executive Orders 14042 and 14043, which mandated COVID-19 vaccinations for all federal employees and federal contractors. Additionally, the Centers for Medicare & Medicaid Services issued regulations requiring vaccinations for all staff at healthcare facilities participating in Medicare or Medicaid. And soon, private companies followed suit. The Occupational Safety and Health Administration issued regulations that all employers with more than 100 employees require vaccination or be subject to mandatory, weekly tests, with violators facing steep fines. The government's mission was stated as: "get more people vaccinated, or prolong this pandemic and its impact on our country."

<sup>&</sup>lt;sup>7</sup> Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020).

<sup>&</sup>lt;sup>8</sup> Exec. Order No. 14042, 86 Fed. Reg. 50989 (Sept. 9, 2021), revoked by Executive Order No. 14099, 88 Fed. Reg. 30891 (May 15, 2023); Exec. Order No. 14043, 86 Fed. Reg. 50989 (Sept. 9, 2021), revoked by Executive Order No. 14099, 88 Fed. Reg. 30891 (May 15, 2023).

<sup>&</sup>lt;sup>9</sup> See Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555, 42 C.F.R. §§ 416, 418, 441, 460, 482–86, 491, 494 (Nov. 5, 2021).

<sup>&</sup>lt;sup>10</sup> See, e.g., Sambrano v. United Airlines, Inc., 19 F.4th 839, 839 (5th Cir. 2021) (Ho, J., dissenting) ("United Airlines claims that it made the 'business judgment' that every employee must obtain a COVID-19 vaccine . . . ."); see also Haley Messenger, From McDonald's to Goldman Sachs, here are the companies mandating vaccines for all or some employees, NBC News (Updated Nov. 16, 2021).

<sup>&</sup>lt;sup>11</sup> See generally, Occupational Safety and Health Administration, RIN 1218-AD42, Docket No. OSHA-2021-0007, Dept. of Labor (Nov. 5, 2021) (fines set at nearly \$14,000 per occurrence).

<sup>&</sup>lt;sup>12</sup> See Statement by President Joe Biden on Vaccination Requirements (Nov. 4, 2021), available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/statement-by-president-joe-biden-on-vaccination-requirements/#:~:text=Vaccination%20is%20the%20single%20best,requirements%20%E2%80%93% 20and%20they%20are%20working. (announcing OSHA policy for 100+ employee mandate).

Significant aspects of civil society — from school attendance to family vacations — hinged on vaccination status. <sup>13</sup> By early 2023, more than 5.5 billion people (about 72.3 percent of the *world* population) had received a dose of a COVID-19 vaccine, <sup>14</sup> including more than 270 million Americans. <sup>15</sup> Defendants have consistently asserted that "COVID-19 vaccines are safe and effective," "recommends everyone ages 6 months and older get an updated COVID-19 vaccine," <sup>16</sup> and added the COVID-19 vaccine to standard Child and Adolescent Immunization Schedule. <sup>17</sup>

## B. The V-safe Program

Contemporaneous with the rollout, Defendants launched the V-safe program to monitor vaccine safety in real time. V-safe employs a smartphone-based application allowing participants to voluntarily enroll and report their (or a dependent's) health after vaccination. ECF No. 29 at 12–13. V-safe collects basic personal information (*e.g.*, name, mobile number, date of birth, sex, zip code) and the vaccine dose(s) he or she has received. *Id.* at 13. To preserve confidentiality, each participant is assigned a registrant code permitting an analyst to connect the participant's various

<sup>&</sup>lt;sup>13</sup> See ECF No. 1 at 4; see, e.g., Zack Gould, States Take Action on Vaccine Mandates in Schools, Nat'l Academy for State Healthy Pol'y (Nov. 9, 2021) (noting California and Illinois require students be vaccinated against COVID-19 to attend school; Hawaii and the District of Columbia required high school students to be vaccinated against COVID-19 to participate in athletics); OpenTable, Restaurants in the U.S. That Require COVID-19 Vaccination for Indoor Dining (Sept. 14, 2021) (listing restaurants available on the reservation platform that require proof of vaccination to dine); Zoe Read & Alan Yu, Which places will require proof of a COVID-19 vaccine? And should they?, WHYY (Apr. 5, 2021) (noting that the Miami Heat, New York Knicks, and New York Rangers require proof of vaccination or a negative COVID-19 test before allowing fans to attend games); Michelle Baran, These Hawai'i, Caribbean, and New York Hotels Now Require Vaccination, AFAR (Sept. 15, 2021) (hotels in various vacation destinations in the United States require proof of COVID-19 vaccination for guests).

<sup>&</sup>lt;sup>14</sup> Josh Holder, Tracking Coronavirus Vaccinations Around the World, N.Y. TIMES (March 13, 2023).

<sup>&</sup>lt;sup>15</sup> As of May 9, 2023, approximately 81.39% of Americans had received at least one dose and 69.47% had completed a primary series. *See* Centers for Disease Control and Prevention, *COVID-19 Vaccinations in the United States*, COVID Data Tracker (Updated May 11, 2023).

<sup>&</sup>lt;sup>16</sup> See, e.g., CDC: Safety of COVID-19 Vaccines (Updated Nov. 3, 2023), available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.

<sup>&</sup>lt;sup>17</sup> CDC: Child and Adolescent Immunization Schedule by Age, available at https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html (recommending "1 or more doses of updated (2023–2024 Formula) [COVID-19] vaccine" at 6 months of age).

surveys without compromising his or her identity. The application sends text messages to the participant with individualized links to the web-based health check-in surveys. *Id.* The surveys are administered: (1) daily for seven days; (2) weekly for five weeks; and (3) at three-, six-, and twelve-month intervals. *Id.* This schedule repeats with each subsequent dose or booster. Questions include ten pre-specified CTB answer choices for a "Symptom Check" (*e.g.*, chills, headache, and nausea) and "Health Impact" (related to ability to work, perform normal activities, treatment or hospitalization). *See* ECF No. 10 at 78. The check-the-box data was released pursuant to separate FOIA litigation. *See Informed Consent Action Network v. Centers for Disease Control and Prevention, et al.*, Civil Action No. 1:22-CV-481-RP, ECF No. 19 (W.D. Tex. Sept. 8, 2022).

Each survey also includes optional free-text fields for "[a]ny other symptoms or health conditions you want to report" and "please describe" regarding healthcare treatment or hospital visits. *See* ECF No. 10 at 78. There are approximately 7.8 million responses, limited to 250 characters in length. <sup>18</sup> These FTRs are the subject of the present litigation. Plaintiff alleges the bifurcated data collection method was designed to restrict reports of adverse events to the free-text entries, suppress the number of reported adverse events, render that data difficult to standardize, and thus curate a misleading health and safety profile of the COVID-19 vaccine — that it is "safe and effective."

Notably, V-safe is not synonymous with other reporting systems maintained by Defendants, including the Vaccine Adverse Event Reporting System ("VAERS"). VAERS detects and characterizes "rare and unexpected conditions," ECF No. 29 at 40, while V-safe captures common — even expected — symptoms in the check-the box responses and "any other" symptoms in the free-text fields. While "VAERS data is processed and made publicly available,"

<sup>&</sup>lt;sup>18</sup> Defendants explain that two free-text fiends were inadvertently designed to collect up to 4,000 characters per response but were modified in June 2021 to capture only the 250-character max. *See* ECF No. 30 at 11.

none of the V-safe data is included in the VAERS disclosure. *Id.* Additionally, Defendants are in the process of converting all free-text responses to standardized medical code ("MedDRA") and have released some 5 million converted entries. *See* ECF No. 39 at 12. Thus, release of the V-safe free-response data, as requested, is separate from the check-the-box and the standard VAERS disclosures.

# C. Plaintiff's FOIA Request

While "Trust the Science" became something of a national slogan, <sup>19</sup> the American public's trust in science and scientists are at an all-time low. <sup>20</sup> It is with this background that Plaintiff aims to further the ideals pledged by the Biden-Harris administration: to "Promote trust, transparency, common purpose, and accountability in our government" by making available for public access — and particularly for independent scientific and medical research — all of the relevant health data collected through the V-safe program. As the check-the-box data has already been released, it is the free-text response data Plaintiff seeks.

Plaintiff "is a nonprofit that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in the CDC's v-safe database." ECF No. 1 at 7. The group is comprised of medical professionals including practitioners, researcher, and educators. *Id.* The nonprofit is a registered Texas Domestic Non-Profit Corporation with its sole headquarters and principal place of business in Amarillo, Texas 79101. *Id.* at 6; ECF No. 1-7 at 93. Plaintiff

The White House: COVID-19, The Biden-Harris plan to beat COVID-19, available at https://www.whitehouse.gov/priorities/covid-19/ ("The Biden-Harris administration will always [l]isten to science."); see also Nate Hochman, Trust the Science?, National Review (Nov. 29, 2021), available at https://www.nationalreview.com/corner/trust-the-science/.

<sup>&</sup>lt;sup>20</sup> See e.g., Brian Kennedy & Alec Tyson, Americans' Trust in Scientists, Positive Views of Science Continue to Decline, Pew Research Center (Nov. 14, 2023).

<sup>&</sup>lt;sup>21</sup> The White House: COVID-19, The Biden-Harris plan to beat COVID-19, *supra* note 9.

maintains a website — www.drsforchoice.org — intended to facilitate publication of the free-text data in anticipation of production pursuant to the FOIA request or a court order.

On January 3, 2023, Plaintiff submitted a FOIA request with Defendants pursuant to 5 U.S.C. §§ 552(a)(6) and (a)(4). *See* ECF No. 30 at 23–28.<sup>22</sup> Plaintiff's request description was: "All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded." *Id.* at 23. Further, Plaintiff acknowledged that redaction may be necessary and therefore requested Defendants "segregate and disclose" the non-exempt portions. *Id.* at 28. Plaintiff also requested expedited processing and waiver of associated fees. *Id.* 25.

The CDC immediately denied expedited processing and waiver of fees, and asserted that "unusual circumstances" warranted an extension of time to respond to the request. *Id.* at 30–31. Thereafter, Defendants issued a final determination to withhold all the free-text response entries because many free-text responses included unsolicited personally identifiable information ("PII") — like names, birthdates, and social security numbers — and Defendants lack of resources to manually review the data to segregate the non-exempt portions. *Id.* at 33–34.

Plaintiff administratively appealed. *Id.* at 36–51 (appeal of final determination), 38–149 (appeal of fee waiver). When Defendants did not resolve the appeals within the time limits prescribed by 5 U.S.C. §§ 552(a)(6)(A)(ii) and (a)(6)(B)(i), the matter because immediately justiciable. On July 3, 2023, Defendants notified Plaintiff that they would cease processing the FOIA final determination appeal because Plaintiff had filed suit in this Court. *Id.* at 55–56 (citing 45 C.F.R. § 5.63). Also on July 3, 2023, Plaintiff received untimely notice that Defendants had

<sup>&</sup>lt;sup>22</sup> "Defendants respectfully refer the Court to [the letters] for a true and complete statement of [their] contents." ECF No. 26 at 4. Accordingly, the Court reviews the FOIA correspondences filed in Defendants' appendix at ECF No. 30.

administratively closed the fee waiver appeal as moot because costs incurred were de minimis. *Id.* at 153. Apparently, on April 12, 2023, Defendants attempted to email Plaintiff regarding the fee waiver appeal, but when the email was "undeliverable," *see id.* at 157, Defendants did not attempt to notify Plaintiff for nearly three months. In the interim, Plaintiff filed suit.

#### LEGAL STANDARD

# A. Modified Summary Judgment Standard in the FOIA Context

The FOIA framework is as follows: First, a requester files a "request for records" that is "sufficiency specific and made in accordance with published procedures for submitting such requests." *Nat'l Sec. Counselors v. C.I.A.*, 898 F. Supp. 2d 233, 254 (D.D.C. 2012) (quoting 5 U.S.C. § 552(a)(3)(A)). Second, the agency must make "reasonable efforts" to search for responsive records. *Id.* Once identified, the agency "shall make the records promptly available." *Id.* An agency, however, must "withhold production of requested records" or "information [that] is exempt from disclosure," *Batton v. Evers*, 598 F.3d 169, 175 (5th Cir. 2010); *Riley v. Fenty*, 7 A.3d 1014, 1018 (D.C. Cir. 2010); *Hyatt v. U.S. Pat. & Trademark Off.*, No. 18-CV-2800(TSC), 2022 WL 1718983, at \*1 (D.D.C. May 27, 2022) (citing 5 U.S.C. § 552(b)) — *e.g.*, "medical files and similar files" that "would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). "[T]he agency has the burden to prove de novo that the information [requested] is exempt from disclosure" and must be withheld. *Batton*, 598 F.3d at 175.

An asserted exemption does not end the inquiry. FOIA requires that "[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt . . . ." 5 U.S.C. § 552(b). Thus, an agency may be compelled to review, redact, and then produce all but the exempted portions of responsive records, documents, and information. The limiting principle is that an agency need not comply with a request that

imposes an "unreasonable burden" on the agency. *Mead Data Ctr., Inc. v. U.S. Dep't of Air Force*, 566 F.2d 242, 260 (D.C. Cir. 1977). If the information cannot be segregated — or cannot be segregated without "unreasonable burden" — the agency bears the burden to explain why beyond conclusory assertions. *See Church of Scientology of Tex. v. I.R.S.*, 816 F. Supp. 1138, 1162 (W.D. Tex. 1993) (internal marks omitted).

When ruling on FOIA summary judgment motions, federal courts must be mindful of FOIA's purpose: to "pierce the veil of administrative secrecy," "open agency action to the light of public scrutiny," and "promote the disclosure of information, not to inhibit it." *Batton*, 598 F.3d at 175 (quoting *Dep't of the Air Force v. Rose*, 425 U.S. 352, 361 (1976)); *Riley*, 7 A.3d at 1018 (internal marks omitted). Accordingly, "the provision of the Act giving citizens the right of access are to be generously construed, while the statutory exemptions from disclosure are to be narrowly construed, with ambiguities resolved in favor of disclosure." *Riley*, 7 A.3d at 1018 (internal marks omitted); *Nat'l Ass'n of Home Builders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002) (FOIA reflects "a general philosophy of full agency disclosure unless information is exempted under clearly delineated statutory language."). "The district court must analyze all underlying facts and inferences in the light most favorable to the FOIA requester. *Ayuda, Inc. v. Fed. Tr. Comm'n*, 70 F. Supp. 3d 247, 259 (D.D.C. 2014) (internal marks omitted).

Courts generally grant an agency's motion for summary judgment "only if the agency proves that it has fully discharged its FOIA obligations," which may mean "the agency identifies the documents at issue and explains why they fall under exemptions." *Id.* (internal marks omitted); *Cooper Cameron Corp. v. U.S. Dep't of Labor, OSHA*, 280 F.3d 539, 543 (5th Cir. 2002). The agency often makes this explanation in an affidavit "concerning the agency's determination as to technical feasibility" — and courts "accord substantial weight" to such an affidavit. *Ayuda*, 70 F.

Supp. 3d at 272; 5 U.S.C. § 552(a)(4)(B). Because the agency bears the burden to establish any applicable exemption, conclusory and generalized assertions that documents are exempt from disclosure are insufficient — even if the FOIA requester has not controverted that assertion. *Id.* (citing *Cooper Cameron Corp. v. U.S. Dep't of Labor, OSHA*, 280 F.3d 539, 543 (5th Cir. 2002)). Likewise, blanket claims that a mass of documents are exempt from disclosure are impermissible. *Vaughn v. Rosen.* 484 F.2d 820, 825 (D.C. Cir. 1973).

#### B. Standing to Bring a FOIA Action

"Any person" can make a FOIA request. 5 U.S.C. § 552(a)(3). Subject to exhausting administrative appeal requirements, "[a]nyone whose request for specific information has been denied has standing to bring an action under FOIA." *Nat'l Sec. Counselors v. C.I.A.*, 898 F. Supp. 2d 233, 254 (D.D.C. 2012) (internal marks omitted). "The requester is injured-in-fact for standing purposes because he did not get what the statute entitled him to receive." *Id.* 

# 1. Time Limits for FOIA Requests and Appeals

By default, an agency must determine whether to comply with a FOIA request within twenty working days. 5 U.S.C. § 552(a)(6)(A)(i). The same timeframe operates with respect to any appeal. 5 U.S.C. § 552(a)(6)(A)(ii). If certain specified "unusual circumstances" exist, the agency may extend its response by an additional ten working days. 5 U.S.C. §§ 552(a)(6)(B)(i), 552(a)(6)(B)(iii) (defining "unusual circumstances" to include retrieval of records maintained elsewhere, voluminous amounts of separate and distinct records, and the need to consult with another agency). Thus, thirty working days operates as the outer limit unless the agency notifies the requester that "the request cannot be processed within the time limits specified" and provides the requester an opportunity to: (1) "limit the scope of the request"; or (2) arrange "an alternative time frame for processing the request or a modified request." 5 U.S.C. § 552(a)(6)(B)(ii).

# 2. Expedited Processing of a FOIA Request

Federal agencies generally process FOIA requests on a first-in, first-out basis. See Open Am. v. Watergate Special Prosecution Force, 547 F.2d 605, 616 (D.C. Cir. 1976); see also ECF No. 30 at 53 ("Each appeal is handled on a first-in, first-out basis . . . ."). However, sometimes agencies must expedite processing for certain requests — bringing them to the front of the queue. See 5 U.S.C. § 552(a)(6)(E)(i)(I); Daily Caller v. U.S. Dep't of State, 152 F. Supp. 3d 1, 8 (D.D.C. 2015); Pub. Health & Med. Pros. for Transparency v. Food & Drug Admin., No. 4:22-CV-0915-P, 2023 WL 3335071, at \*1 (N.D. Tex. May 9, 2023). A requester is entitled to expedited processing if it shows a "compelling need." See 5 U.S.C. § 552(a)(3)(6)(E)(i)(I). A "compelling need" means: (1) there is "an imminent threat to the life or physical safety of an individual"; or (2) for "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity." See 5 U.S.C. § 552(a)(3)(6)(E)(v)(I)-(II). If an agency denies a request for expedited processing under FOIA, the requester may file with the district court and seek immediate judicial review. 5 U.S.C. § 552(a)(6)(E)(iii). District courts have "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld." 5 U.S.C. § 552(a)(4)(B). Determinations by the district court are made de novo. See Bloomberg, L.P. v. FDA, 500 F. Supp. 2d 371, 374 (S.D.N.Y. 2007).

## 3. Fee Waivers for FOIA Requests

Production of requested records may involve costs and fees. See 5 U.S.C. § 552(a)(4)(A)(i). However, a FOIA requester is entitled to a fee waiver if: (1) "disclosure of the information is in the public interest," meaning disclosure "is likely to contribute significantly to public understanding of the operations or activities of the government"; and (2) disclosure "is not

primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). Matters related to a fee waiver are decided by the district court de novo — considering only the record before the agency. 5 U.S.C. § 552(a)(4)(A)(vii).

#### **APPLICATION**

# A. Defendants must produce the free-text data subject to redaction of PII as required by FOIA Exemption 6.

The development and distribution of the COVID-19 vaccine was one of the greatest endeavors in recent history. Predictably, the American public now seeks access to COVID-related papers to ensure that relevant government policies were — and still are — supported and justified by the available data. That is precisely what FOIA contemplates and facilitates.

It is also what Defendants expected and envisioned for V-safe — at least initially. V-safe protocol intended that "[a] final data set . . . with deidentified data will be made available for external data requests or through Freedom of Information Act (FOIA) requests." V-Safe Protocol: April 18, 2022, version 5, at 12, available at https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V5-508.pdf (last viewed December 27, 2023); *see also* ECF No. 35 at 18. However, Defendants now argue that because the pandemic lasted longer than expected and "the vaccination program in the United States evolved to include recommendations for booster doses . . . the V-safe application collected considerably more data and was operational for a longer period than initially anticipated." ECF No. 30 at 20–21. The simple reason Defendants denied Plaintiff's production request is the 7.8 million free-text response entries are allegedly too numerous for the agency's limited resources. *See* ECF No. 30 at 33. While the burden to produce the requested free-text responses may be heavy, this Court does not find that it is unreasonable. <sup>23</sup>

<sup>&</sup>lt;sup>23</sup> In 2024, American citizens may be *more* interested in COVID data following Dr. Francis Collins's statements on the "public-health mindset," which were printed in several media publications in December 2023. *See, e.g.*, Ed. Bd. *Francis Collins Has Regrets, but Too Few*, WALL St. J. (Dec. 29, 2023), available at

## 1. Plaintiff submitted an appropriately narrow FOIA request.

Plaintiff's request seeks:

"All data obtained from v-safe users/registrants form the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded.) Date range: 10/01/2020–12/31/2022."

ECF No. 30 at 33. The request is as narrow as possible without compromising the meaningfulness of the request, excludes the already-released check-the-box data, and acknowledges that redacting exempted material may be necessary. *See id.* at 23, 28. Thus, Defendant's form language inviting Plaintiff to "consider narrowing the scope of your request to limit the number of responsive records" is of no effect. *Id.* at 30.

## 2. <u>Defendants conducted an adequate search.</u>

An agency must demonstrate "that it has conducted a search reasonably calculated to uncover all relevant documents." *Weisberg v. U.S. Dep't of Justice*, 705 F.2d 1344, 1351 (D.C. Cir. 1983); *see also Batton*, 598 F.3d at 176. The parties do not dispute that Defendants conducted an adequate search, identifying the complete, known sum of all responsive records — the 7.8 million V-safe free-text responses together with their respective registrant codes. *See* ECF Nos. 9 at 27–32, 29 at 19–20, 35 at 2.

https://www.wsj.com/articles/francis-collins-covid-lockdowns-braver-angels-anthony-fauci-great-barrington-declaration-f08a4fcf; John Fund, *Officials Now Admit the Disaster of Their Covid Policies*, NATIONAL REVIEW (Jan. 4, 2024), available at https://www.nationalreview.com/2024/01/officials-now-admit-the-disaster-of-their-covid-policies/ ("If you're a public-health person and you're trying to make a decision, you have this very narrow view of what the right decision is, and that is something that will save a life. It doesn't matter what else happens. So you attach infinite value to stopping the disease and saving a life. You attach a zero value to whether this actually totally disrupts people's lives, ruins the economy, and has many kids kept out of school in a way that they never quite recovered from. . . . This is a public-health mindset. And I think a lot of us involved in trying to make those recommendations had that mindset, and that was really unfortunate. It's another mistake we made. Okay.")

# 3. Exemption 6 applies to any PII present in the responsive records.

Exemption 6 prohibits dissemination of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). The Supreme Court explained the "exemption [was] intended to cover detailed Government records on an individual which can be identified as applying to that individual." *U.S. Dep't of State v. Washington Post Co.*, 456 U.S. 595, 601–02 (1982). "If the request includes such personal information," courts must examine "whether release of the information would constitute a clearly unwarranted invasion of that person's privacy." *Sherman v. U.S. Dep't of Army*, 244 F.3d 357, 361 (5th Cir. 2001).

The parties do not dispute that it would be improper for Defendants to produce any PII present in responses or even what may constitute PII.<sup>24</sup> In fact, Plaintiff's request contemplated that records would need to be reviewed and redacted. ECF Nos. 29 at 39 ("While the Free-Text Responses were not specifically drafted to capture [PII], V-safe participants did include PII in these fields when answering the questions, 35 at 6 ("Plaintiff does not contest that [PII] should be redacted from the data produced."). Any information that affects the likelihood that a specific person be individually identified must be redacted and withheld.

Importantly, a participant's registrant number<sup>25</sup> and generalized demographic information are *not* PII. *See Ayuda*, 70 F. Supp. 3d at 271 (finding disclosure of five-digit zip code did not "actually or potentially affect[] the likelihood that the complainant will be identified"). The type

<sup>&</sup>lt;sup>24</sup> While an agency must ordinarily produce a *Vaughn* index for in-camera review, the Court finds such review unnecessary. Because the parties do not dispute the kind of information is subject to exemption and redaction, there is no need for the Court to conduct a "review of the agency's decision." *See Coldiron v. U.S. Dep't of Just.*, 310 F. Supp. 2d 44, 46 (D.D.C. 2004).

<sup>&</sup>lt;sup>25</sup> The registrant ID numbers have already been released ancillary to the check-the-box data pursuant to separate FOIA litigation. An anonymous registrant ID number, without more, does not identify a particular person. Rather, some types of PII *could* identify a particular person, so that information must be withheld.

of information that must be reviewed for, redacted, and withheld from production must "actually or potentially affect[] the likelihood that [a V-safe participant] will be identified" individually. *Id.*Thus, unsolicited bits of information — like names, birthdates, social security numbers, employer, and location where he or she received the vaccine if sufficiently specific (i.e., "ABC Pharmacy on Main Street in Amarillo" but not "Wal-Mart Pharmacy") — that may be included in some V-safe responses must be redacted. *See* ECF No. 30 at 11–12 (listing examples of PII found within Free-Text Responses, organized by registrant codes). Defendants aver that sex and zip code constitute PII, but that is not the case. The pieces of information exempt from disclosure by Exemption 6 must risk identifying a specific person — for instance, a telephone number and first name. Descriptions that do not personally identify a specific person are not exempted by Exemption 6.

# 4. Production of the redacted free-text data is not unreasonably burdensome.

The primary dispute is whether the review, redaction, and production process amounts to an unreasonable burden. More specifically, whether the exempted PII contained within some free-text data is reasonably capable of segregation from the non-exempt remainder. Defendants contend "the non-exempt information within the Free-Text Responses is not *reasonably* segregable, because having to review and redact 7.8 million Free-Text Responses to segregate non-exempt information would impose an unreasonable burden on the agency." ECF No. 29 at 32. Typically, courts discuss "the physical difficulty of segregating exempt information within the relevant records." *Ayuda*, 70 F. Supp. 3d at 276 (citing *Int'l Counsel Bureau v. U.S. Dep't of Def.*, 864 F. Supp. 2d 101, 106–07 (D.D.C. 2012)).

Defendants do not argue that the information is *physically* incapable of segregation. Rather, Defendants claim they do not have the manpower to comply. ECF No. 29 at 39 (The FOIA Office "does not have the resources to process this request in-house."). Specifically, Defendants aver that

the entirety of "CDC's FOIA Office comprises *thirteen* FOIA analysts who are responsible for responding to all FOIA requests from receipt to completion of any administrative appeal, as well as assisting with any related litigation." ECF No. 29 at 36 (emphasis added). Plaintiff, on the other hand, contends that programs for automated electronic data review are available and capable of minimizing the burden of manual review and, moreover, the task is not as weighty as Defendants describe. ECF No. 35 at 17.

In support, Defendants marshal CDC FOIA Officer Roger Andoh's declaration, ECF No. 30 at 4–21, wherein he opines that review would take a single analyst 59 years, *accord id.* at 14 *with* ECF Nos. 29 at 36. While "[a]n agency may establish reasonableness through affidavits" — which FOIA instructs should be given substantial weight — a court may nonetheless reject the affiant's determination if "there were some reason to believe that the documents could be located [and produced] without an unreasonably burdensome search." *Goland v. C.I.A.*, 607 F.2d 339, 353 (D.C. Cir. 1978). Having reviewed Andoh's declaration, the Court does not find it ultimately persuasive.

Instead, this Court finds that production is not unreasonably burdensome for at least four reasons: (1) the requested records are not so voluminous; (2) only a small percent of records will require any redaction; (3) the redaction process is largely straightforward and capable of automated assistance; and (4) blanket exemption claims covering a mass of records are impermissible. For those reasons, Defendants are not absolved of their responsibility to produce the redacted free-text responses.

i. The responsive records are not so voluminous as to present an unreasonable burden.

First, Defendants are correct that the sheer volume of responsive records may support of finding of unreasonable burden, especially when considered with an agency's limited resources.

See, e.g., Ayuda, 70 F. Supp. 3d 277 (finding manually reviewing twenty million responsive records was unreasonably burdensome). However, Defendants' asserted caselaw is misleading as applied. Defendants cite several cases where courts determined that production and/or post-production review of voluminous records amounted to an unreasonable burden. ECF No. 29 at 33–34; see Shapiro v. U.S. Soc. Sec. Admin., 525 F. Supp. 3d 528, 539–40 (D. Vt. 2021) (finding FOIA request unduly burdensome as it would require line-by-line manual review of more than 1.5 million pages); Nat'l Day Laborer Org. Network v. U.S. Immigr. & Customs Enf't, No. 16-CV-387, 2017 WL 1494513, at \*14–15 (S.D.N.Y. Apr. 19, 2017) (finding undue burden where responsive records could number up to 1.3 million pages, with review taking up to an estimated 1,300 weeks). Each of those cases considered the number of pages while this case concerns 250-character fields.

But the Court must compare and units of measurement, not merely naked numerals. Courts have considered myriad units of measure in the FOIA context. *See, e.g., Long v. Immigr. & Customs Enf't*, 149 F. Supp. 3d 39, 56 (D.D.C. 2015) (considering "1.8 million songs on an iPod") *Goland*, 607 F.2d at 353 (considering "84,000 cubic feet of documents"). Each of Defendants' asserted cases considered a voluminous number of *pages*. However, Defendants report the free-text entries in terms of *characters. See, e.g.*, ECF No. 30 at 11. The free-text entries were limited to 250 characters each. For comparison, X (a/k/a "Twitter") permits most users to tweet up to 280-characters. *Thus, the parties functionally dispute Defendants ability to review and redact 7.8 million tweets*, not *pages*.

<sup>&</sup>lt;sup>26</sup> But see, supra note 18. Defendants have not explained how many responses — if any — actually exceeded 250 characters.

<sup>&</sup>lt;sup>27</sup> See Nocholas Reimann, FORBES: Twitter Boosts Character Limit to 4,000 For Twitter Blue Subscribers (Feb. 9, 2023), available at https://www.forbes.com/sites/nicholasreimann/2023/02/08/twitter-boosts-character-limit-to-4000-for-twitter-blue-subscribers/?sh=4554c86c5ab8 (explaining how "non-subscribers," approximately 99.8% of users, are limited to 280 characters per tweet).

Affording Defendants the greatest mathematical latitude by assuming *each* free-text response utilized the full 250 characters, the 7.8 million free-text responses yields 1,950,000,000 characters. Considering an average page of text — using 12-point Times New Roman font, single spaced, and one-inch margins — an average page contains approximately 3,000–3,276 characters. The 1,950,000,000 characters would yield approximately 595,238–650,000 pages. Considering the COVID-19 vaccine was the largest federal project in recent history, that is not surprising. This Court does not find that — at most — 650,000 pages amounts to an unreasonable burden. *See Pub. Health & Med. Pros. for Transparency*, 2023 WL 3335071, at \*1 n.1 (leaving unchanged the expected end date for producing all documents despite the actual number of documents being 1.2 million rather than 450,000 as the agency previously estimated). Of course, this is likely an excessive overestimation.

But in the FOIA context, "[t]he district court must analyze all underlying facts and inferences in the light most favorable to the FOIA requester." *Ayuda*, 70 F. Supp. 3d at 259. The comparable responses from V-safe's motivation survey averaged a mere 35 characters. ECF No. 1 at 80.<sup>29</sup> Thus, assuming each free-text response is 35 characters like the motivation survey, the total production could be as little as 273,000,000 characters yielding a mere 83,333–91,000 pages.

FOIA Officer Andoh estimates that manual analysis would "take about 123,564 workhours to complete." ECF No. 30 at 16. At the high end (650,000 pages) that is approximately 11.5 work-

<sup>&</sup>lt;sup>28</sup> Plaintiff represents 3,276 characters per page. *See* ECF No. 35 at 17. Considering the common metric of 500 words per page double-spaced, or 1,000 single-spaced, and average word length at 6 characters (including a space), the range is appropriate for estimation. *See, e.g.*, Wylie Communications: *What's the best length of a word online?*, available at https://www.wyliecomm.com/2021/11/whats-the-best-length-of-a-word-online/ (reporting average word lengths of various publications as between 4 and 6 characters).

<sup>&</sup>lt;sup>29</sup> The Court acknowledges Defendants' opposition to analogizing from the motivation survey, *see* ECF No. 39 at 9, and notes that Defendants failed to contest Plaintiff's allegation that the V-safe free-text fields are likely to be of comparable length. Regardless, the Court uses this metric only for calculating a low-end comparison.

minutes to review each page. At the low end (83,333 pages), it would be an hour and a half per page of text.

ii. Only a small percent of the records are likely to contain any PII at all.

Second, Defendants have marshaled evidence that approximately 7% of responses will contain unsolicited PII. *See* ECF No. 30 at 11–12. Accordingly, while screening all 7.8 million responses is necessary, approximately 93% will require no reduction at all.

iii. Any necessary redactions are simple and capable of automated assistance.

Third, the required redactions are not complex or nuanced. True, a less voluminous production that requires heavy post-production review and redaction may constitute an unreasonable burden. *See Vietnam Veterans of Am. Conn. Greater Hartford Ch. 120 v. DHS*, 8 F. Supp. 3d 188, 203–04 (D. Conn. 2014) (finding undue burden where 26,000 fifty-page packets required heavy redactions). However, the present case does not entail particularly complex redactions. Rather, the redacted information is part-and-parcel of many automated programs utilized by law firms to screen large quantities of documents during discovery. Defendants may deploy automated review and redaction of the free-text responses, significantly reducing the workload for Defendants' analysts. Indeed, the data is already stored in digital form. *See* ECF No. 29 at 13–14 (explaining how V-safe data is stored and transmitted for review).

For precisely this reason, Congress passed the Electronic Freedom of Information Act ("E-FOIA") Amendments. Pub. L. No. 104–231 § 2(a)(6); *People for the American Way*, 451 F. Supp. 2d 6, 13 (D.D.C. 2006). E-FOIA instructs agencies to "use new technology to enhance public access to agency records and information." *People for the American Way*, 451 F. Supp. 2d at14 (quoting E-FOIA § 2(a)(6)). New technology provides alternative search methodologies that

<sup>&</sup>lt;sup>30</sup> Notably, *Vietnam Veterans* still concerned some 1.3 million pages  $(26,000 \times 50 = 1,300,000)$  — approximately double the high-end of the estimated record requested here.

substantially reduce the burden imposed on an agency compared to historic manual review. *See Freedom Watch, Inc. v. Nat'l Sec. Agency*, 783 F.3d 1340, 1345 (D.C. Cir. 2015) ("[N]ot only does FOIA expressly permit automated searches," but "search" in the context of 5 U.S.C. § 552 "means to review, manually or by *automated means.*); *cf. Pub. Citizen, Inc. v. Dep't of Educ.*, 292 F. Supp. 2d 1, 6–7 (D.D.C. 2003) (ordering a search of 25,000 files for irregularly kept data, despite the need for manual review). Insofar as Defendants argue that "manual review" would impose an unreasonable burden, this Court finds that it would — especially employing "automated means." *Freedom Watch*, 783 F.3d at 1345.

Moreover, some 20 years after *Public Citizen, Inc.*, the technology for automated document review has advanced to largely nullify concerns about manual review and even simple search parameters like name, birthdates, social security numbers, phone numbers, and email addresses — the types of PII at issue here. The automated processes acknowledged by both parties, expressly contemplated by FOIA, and mandated by E-FOIA, are capable of substantially reducing the costs and time required to review and redact for exempted PII.

Defendants also aver internal process complicate the matter. First, CDC's FOIA Office comprises only thirteen analysts. ECF No. 30 at 15. Second, Defendants' practice entails "another manual, line-by-line review" by "either a senior FOIA analyst or Team Lead." ECF No. 29 at 35. While neither Plaintiff nor this Court dispute the Defendants' alleged allocation of FOIA staff, "the number of resources an agency dedicates to such requests does not dictate the bounds of an individual's FOIA rights." *Pub. Health & Med. Pros. for Transparency*, 2023 WL 3335071, at \*2 (citing *Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605, 621 (D.C. Cir. 1976) (Leventhal, J., concurring). Instead, this Court must ensure that the fullest possible disclosure of

the information sought is timely provided — as "stale information is of little value." *Id.* (quoting *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988)).

iv. Blanket exemption claims covering a mass of records are impermissible.

Fourth, Defendants' decision to withhold all free-text responses because some contain PII is tantamount to an impermissible blanket claim. Vaughn v. Rosen compels agencies to both segregate and identify the rationale for withholding records that are not segregable and disclosable. See 484 F.2d 820; see also Ray v. Turner, 587 F.2d 1187 (D.C. Cir. 1978). "[A]n entire document is not exempt merely because an isolated portion need not be disclosed. Thus, the agency may not sweep a document under a general allegation of exemption, even if that general allegation is correct with regard to part of the information." Vaughn, 484 F.2d at 825. "An agency must therefore redact exempt information and produce any relevant non-exempt information." Coldiron, 310 F. Supp. 2d at 47 (citing 5 U.S.C. § 552(b)). An agency claiming information is exempt and incapable of reasonable segregation must "describe what proportion of the information is non-exempt and how that material is disbursed throughout the document." Id. That particularized description ensures "both litigants and judges will be better position[ed] to test the validity of the agency's claim that the non-exempt material is not segregable." Id. (internal marks omitted). To the extent Defendants have particularly described the proportion of affected responses, this Court finds that approximately 7% does not impose an unreasonably burdensome for simple redactions largely capable of automation.

Certainly, blanket claims would be easier for the agency, but convenience is not relevant and segregable portions must be disclosed. *Badhwar v. U.S. Dep't of Air Force*, 622 F. Supp. 1364 (D.D.C. 1985), *order vacated on other grounds*, 829 F.2d 182 (D.C. Cir. 1987). This Court must determine whether segregation is "unreasonable" or merely inconvenient, and then whether the

remaining non-exempt portions are intelligible to warrant production of the redacted records. Simpson v. Vance, 648 F.2d 10, 17 (D.C. Cir. 1980), abrogated by U.S. Dep't of State v. Washington Post Co., 456 U.S. 595 (1982); Mead Data Central, Inc. v. U.S. Dep't of Air Force, 566 F.2d 242, 261 (D.C. Cir. 1977).

Defendants have withheld *all* records because *some* records likely contain *some* exempt material, and segregation would potentially be very inconvenient, considering Defendants' understaffed FOIA office. As addressed, this Court does not find that to be the case. Rather, the exempt PII is reasonably capable of redaction, leaving the remaining non-exempt portions of the free-text responses capable of production. Additionally, what remains will not only be intelligible, but precisely what Plaintiff seeks — the health and symptom information without PII like emails or social security numbers.

Further, if only 7% of free-text responses contain any PII at all, then the remaining 93% should not be categorically withheld. *Cf. Pub. Citizen v. Dep't of State*, 100 F. Supp. 2d 10, 25 (D.D.C. 2000), *rev'd on other grounds, Pub. Citizen*, 276 F.3d at 644–45 ("[T]he fact that the State Department, of its own accord, re-reviewed its withholdings and released certain additional entrie indicates that the agency has been mindful of its obligation to release any segregable information."). Defendants have not evinced similar mindfulness of their obligation.

Therefore, while the burden to review and redact these responses for production may impose a heavy burden on Defendants, this Court does not find that burden to be unreasonable.

## 5. Even if production entails a *heavy* burden, production is still warranted.

Plaintiff argues that release of the data is essential for myriad reasons. Some groups contend they were injured by the vaccine, and without access to the underlying data they cannot meaningfully seek coverage or treatment. *See* ECF No. 1 at 3. Some parents are hesitant to

consent — or even believe they are incapable of consenting — for their minor children to receive the vaccine. *Id.* at 4. Production of the source material is essential for independent researchers to evaluate the vaccines and for medical professionals to provide meaningful treatment to their patients. Some of Plaintiff's members are already engaged in this type of research. ECF No. 30 at 72 ("Many [Freedom Coalition of Doctors for Choice members] share with the public their findings, research, and professional opinions about Covid-19 and related issues.").

Notably, Plaintiff points to several studies published and presented by CDC that rely upon on the V-safe data. See ECF No. 35 at 9–13. All but one of those studies considered only the *first* seven days after receiving a vaccine, and the only study that looked beyond the first week considered just two weeks. Id. at 9 n.2. Defendants do not contest this. See ECF No. 39 at 10. Rather, Defendants dismiss the limited scope of the published studies as just "the time period that some scientists have chosen to use in their research studies." Id. at 11.

Because Defendants structured V-safe to collect health and symptomatic responses for a full year after a vaccine or booster, reviewing that data is of great importance to the public. If "some scientists" — sponsored or platformed by Defendants — "have chosen to use" only the first week or two of data to report the vaccine is safe and effective, then *other* scientists should be permitted to access the data to "pierce the veil of administrative secrecy," "open agency action to the light of public scrutiny," and "promote the disclosure of information." *Batton*, 598 F.3d at 175 (internal marks omitted); *Riley*, 7 A.3d at 1018 (internal marks omitted). Many of the policies previously addressed were enacted because of guidance from Defendants.<sup>31</sup> With billions of taxpayer dollars expended to develop, distribute, administer, and fund messaging campaigns,

<sup>&</sup>lt;sup>31</sup> See generally, Center for Disease Control and Prevention, Guidance Documents, available at https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html (hosting a plethora of guidance documents instructing various entities on best practices to combat the COVID-19 pandemic).

Plaintiff assumes a hefty and viable public interest in examining the raw clinical data. Production of the free-text data will permit independent researchers to put the government agencies to their proof by considering *all* of the available data. *See Judicial Watch v. Rossotti*, 326 F.3d 1309, 1314 (D.C. Cir. 2003) (The question is "whether disclosure of the requested documents is likely to contribute to public understanding of the [the government's COVID-19 operations and activities] — a goal that disclosure will promote regardless of what the documents reveal.").

Additionally, Plaintiff marshalled evidence that some vaccine studies may be misleading or based upon cherry-picked data. *See* ECF No. 9 at 17–18. One study reported that 0.8% to 1.1% of users reported needing medical care according to the check-the-box data. *Id.* at 13, 13 n.4. However, when the raw data was released pursuant to separate FOIA litigation, it showed some 7.7% of V-safe users reported needing medical care and an additional 25% missing school or work or unable to perform normal activities. *Id.* Similarly, Plaintiff alleges the check-the-box data captures only the "symptoms CDC says are normal to occur after vaccination and are actually a sign the vaccine is working." ECF No. 30 at 63. Thus, collecting that data and then profiling the vaccine as safe and effective based was a "pointless" exercise *Id.* Any concerning symptoms would necessarily be restricted only the free-text responses, to date unexamined by independent researchers not sponsored by Defendants.

Finally, rapid vaccination of a huge percentage of the American population is nothing short of astounding, and the endeavor continues. On November 4, 2021, the White House announced that "70 percent of adult Americans are now fully vaccinated" thanks to the Biden Administration's "policies requiring millions of federal employees and federal contractors to be fully vaccinated."<sup>32</sup> As of May 11, 2023, the CDC reports that more than 81% of Americans have

<sup>&</sup>lt;sup>32</sup> The White House: *New OSHA and CMS Rules Mean Two-Thirds of All Workers Now Covered by Vaccination Rules* (Nov. 4, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-

received at least one dose, including nearly 32 million children.<sup>33</sup> Understandably, there is substantial public interest in the data that supported, and continues to support, the government's promotion of the COVID-19 vaccines and boosters.

It bears repeating that "[a]ny person" can make a FOIA request. 5 U.S.C. § 552(a)(3). "[A]s a corollary of these democratic principles," "the specific motives of the party making the FOIA request are irrelevant." *Cooper Cameron Corp.*, 280 F.3d at 547 (internal marks omitted). "[T]he rights of the requester are no different from those that might be asserted by any other third party, such as a neighbor or prospective employer." *Id.* (internal marks omitted). Justice Ginsberg noted this "main rule serves as a check against selection among requesters, by agencies and reviewing courts, according to idiosyncratic estimations of the request's or requester's worthiness." *United States Dep't of Def. v. Fed. Lab. Rel. Auth.*, 510 U.S. 487, 508 (1994) (Ginsburg, J., concurring). Accordingly, the foregoing analysis does not — and need not — vindicate or credential Plaintiff's request. *See Cooper Cameron Corp.*, 280 F.3d at 548 ("[A]lthough we suspect that Cooper seeks the deponent's statements to impeach testimony in the tort suit, our suspicion counts neither in favor of nor against Cooper's FOIA request."). Rather, the motives addressed herein guide this Court in finding that an arguably *heavy* burden is not synonymous with an *unreasonable* burden when viewed in light of the activities and operations of the government in response to COVID-19.

# B. Plaintiff is entitled to expedited processing.

Plaintiff contends that Defendants wrongfully denied its request for expedited processing in the letter dated January 4, 2023. *See* ECF No. 30 at 76. This Court agrees.

administration-announces-details-of-two-major-vaccination-policies/ (last viewed December 21, 2023). (Press Statements and Releases)

<sup>&</sup>lt;sup>33</sup> Centers for Disease Control and Prevention: COVID Data Tracker, COVID-19 Vaccinations in the United States (Data provided by CDC, final update posted May 11, 2023), https://covid.cdc.gov/covid-data-tracker/#vaccinations vacc-people-booster-percent-pop5 (last viewed December 21, 2023).

A requester is entitled to expedited processing if it shows a "compelling need." *See* 5 U.S.C. § 552(a)(3)(6)(E)(i)(I). As relevant here, for "a person primarily engaged in disseminating information," a "compelling need" means "urgency to inform the public concerning actual or alleged Federal Government activity." *See* 5 U.S.C. § 552(a)(3)(6)(E)(v)(I)–(II).

First, Plaintiff is "primarily engaged in disseminating information." 5 U.S.C. § 552(a)(3)(6)(E)(v)(II). The nonprofit entity "was formed and exists for the sole purpose of obtaining and disseminating to the public the v-safe free-text data." ECF No. 1 at 5, 7. Defendants' argument to the contrary is unavailing. The January 4, 2023, letter denying expedited processing simply states: "You have not demonstrated that you are a person primarily engaged in disseminating information." ECF No. 30 at 76. Plaintiff is not actively disseminating information to the public because Plaintiff is not yet in receipt of the information it seeks to disseminate. Defendant's argument renders the subpart meaningless: a FOIA requester could only be "engaged in disseminating information" when he is actively disseminating information, which presupposes the information is already in his possession. Because the expedited processing analysis precedes production, no requester could qualify unless he is engaged in disseminating other information. Nothing in FOIA or the relevant caselaw supports this reading of the statute. Rather, Plaintiff is "engaged in" obtaining information, an essential step that necessarily precedes the dissemination of same.

Second, Plaintiff has shown an urgent need to inform the public about "actual or alleged Federal Government activity" — namely, related to the health and safety of the COVID-19 vaccines and policies. Plaintiff points to the federal government's policies and messaging campaigns designed to promote the public's uptake of vaccines and boosters. *See* ECF No. 9 at 7–8. Plaintiff's initial request specifically cites the recent addition of the COVID-19 vaccine to the

routine childhood immunization schedule and the Biden administration's messaging campaigns specifically aimed at families. ECF No. 30 at 27. And as recent as September 12, 2023, the Biden administration continues to "encourage all Americans to stay up-to-date on their [COVID-19] vaccines."<sup>34</sup>

Additionally, as addressed above, Plaintiff presents evidence that calls into question the claim that the vaccines are safe and effective — or at least the scope of research supporting that claim. "The law is clear that FOIA does not provide requesters with a right to demand an all-encompassing fishing expedition," and courts "need not embark on a time-consuming and costly goose chase in pursuit of phantom reports from the agency." *Cause of Action v. Internal Revenue Service*, 253 F.Supp.3d 149, 160 (D.D.C. 2017). However, Plaintiff's briefing — both in this litigation and what was presented in the FOIA proceedings — sufficiently establish "alleged" activity by the Federal Government sufficient to satisfy 5 U.S.C. § 552(a)(3)(6)(E)(v)(II).

Therefore, because Plaintiff has shown a compelling need, Defendants wrongfully denied its request for expedited processing. *See Pub. Health & Med. Pros. for Transparency*, 2023 WL 3335071, at \*2.

#### C. Plaintiff is entitled to a fee waiver.

A FOIA requester is entitled to a fee waiver if: (1) "disclosure of the information is in the public interest," meaning disclosure "is likely to contribute significantly to public understanding of the operations or activities of the government"; and (2) disclosure "is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). Matters related to a fee waiver are decided by the district court de novo — considering only the record before the agency. 5 U.S.C.

<sup>&</sup>lt;sup>34</sup> Statement from President Biden on FDA and CDC Action on Updated COVID-19 Vaccines (Sept. 12, 2023), available at https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/12/statement-from-president-biden-on-fda-and-cdc-actions-on-updated-covid-19-vaccines/.

§ 552(a)(4)(A)(vii). That record includes Plaintiff's initial request, ECF No. 30 at 23–28, and Plaintiff's appeal of the fee waiver denial, *id.* at 58–149.

Plaintiff has made the requisite showing. Plaintiff explained that it sought the "primary source documentation" to permit independent research as to "the overall safety and efficacy of the COVID-19 vaccines." *Id.* at 59. Notably, the sample size is massive — representing between 3— 4.5% of the vaccinated population — thus permitting particularly accurate research.<sup>35</sup> The V-safe free-text responses will contribute to the public's understanding of the COVID-19 vaccines specifically as to the assertion by Defendants, the Biden administration, and others that the vaccine is "safe and effective" for everyone over six months of age — by providing access to the direct source material to treating physicians, researchers, parents, recipients, and non-recipients. ECF No. 30 at 60. "[D]isclosure of the information will" permit any interested person to research and report "whether CDC properly analyzed the information to detect and evaluate clinically important adverse events and safety issues that impacted its relevant policies or regulatory decisions and recommendations." Id. Further, all Americans continue to be the target audience of marketing and messaging campaigns to promote continued vaccination.<sup>36</sup> Additionally, even if the redacted responses are less useful than extrapolated MedDRA data, a position taken by Defendants, see ECF No. 30 at 12-13 ("[I]t is this robust extrapolated [MedDRA] data of any adverse events . . . that would inform the public as to government activities."), the public nonetheless has

<sup>&</sup>lt;sup>35</sup> Andrade, C. *Sample Size and its Importance in Research*, Indian J. Psychol. Med. 2020; 42: 102–03 ("A sample that is larger than necessary will be better representative of the population and will hence provide more accurate results."); Faber J, Fonseca L.M. *How Sample Size Influences Research Outcomes*, Dental Press J. Orthod. 2014 July–UG; 19(4): 27–29 (describing appropriate methods for retrospective study of very large samples).

<sup>&</sup>lt;sup>36</sup> See, e.g., Pfizer, Inc's recent advertisement series entitled "Got Yours?" featuring various performers, including "Mr. Pfizer" himself — i.e., the Kansas City Chief who also appears in State Farm® commercials and Taylor Swift-related celebrity news.

the right to check the math. Finally, the information is not in Plaintiff's commercial interests, as it expects neither to seek nor gain monetarily from the data. ECF No. 9 at 35.

Therefore, Plaintiff is entitled to a waiver of all fees for production.

#### **CONCLUSION**

For the foregoing reasons, Plaintiff's Motion is **GRANTED** and Defendants' Cross Motion is **DENIED**. Additionally, parties are to comply with the following:

- Defendants are ORDERED to produce all free-text responses, together with the registrant number, redacted personal identifying information as described in this Order, on or before January 15, 2025;
- Defendants must produce batches of the free-text responses on a first-in, first-out basis;
- Defendants are **ORDERED** to comply with the below-listed *minimum* production schedule:
- Defendants can "bank" any processed free-text responses it reviews and redacts in excess of its monthly quota;
- Parties are **ORDERED** to work together in good faith in the production process;
- Concerns regarding production, redaction, or deadlines should be promptly presented to this Court by a joint filing after parties have attempted to resolve the issue;
- On the first of April, July, October, and January, the parties are **ORDERED** to submit a joint status report regarding rate and quality of production, or any other matter that arises.

DUE-BY DATE	TERM MINIMUM	CUMMULATIVE MINIMUM
February 15, 2024	390,000	390,000
March 15, 2024	390,000	780,000
*April 15, 2024	390,000	1,170,000
May 15, 2024	650,000	1,820,000
June 15, 2024	650,000	2,470,000
*July 15, 2024	650,000	3,120,000
August 15, 2024	780,000	3,900,000
September 15, 2024	780,000	4,680,000
*October 15, 2024	780,000	5,460,000
November 15, 2024	780,000	6,240,000
December 15, 2024	780,000	7,020,000
*January 15, 2025	780,000	7,800,000

SO ORDERED.

January 5, 2024.

MATTHEW J. KACSMARYK

UNITED STATES DISTRICT JUDGE